UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

September 25, 2006

**MEMORANDUM**

Subject: Efficacy Review for EPA Reg. No. 464-702, UCARCIDE 42:
DP Barcode: 330310

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell PM 33/ Martha Terry
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: The Dow Chemical Company
171 River Road
Piscataway, NJ 08854

Formulations from Label

| Active Ingredient(s) | % by wt. |
|---|---|
| Glutaraldehyde | 42.5.0% |
| Alkyl ($C_{14}$, 50%, $C_{12}$ 40%, $C_{16}$ 10%) dimethyl benzyl ammonium chloride | 7.5% |
| Inert Ingredients | 50.0% |
| Total | 100.0% |

## I BACKGROUND

The product, UCARCIDE 42 Antimicrobial (EPA Reg. No. 464-702), a registered sanitizer for use on hard, non-porous, non-food contact surfaces in industrial and animal production environments. The product may also be used in formulating products; however, formulators are responsible for providing the Agency with appropriate registration data for formulated products. The applicant requested to amend the registration of this product to add claims for effectiveness against Avian influenza (H5N1) virus, Foot and Mouth Disease virus, Porcine circovirus, and SARS-associated Coronavirus.

Studies were conducted at MicroBioTest, Inc., located at 105 Carpenter Drive in Sterling, VA 20164; Southern Research Institute, located at 2000 Ninth Avenue South in Birmingham, AL 35205; and the Institute for Animal Health, Pirbright Laboratory, located on Ash Road in Pirbright, Surrey GU24 0NF.

This data package contained a letter from the applicant to EPA (dated April 7, 2006), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), four studies (MRID Nos. 468181-01 through 468181-04), Statements of No Data Confidentiality Claims for all four studies, and the proposed label.

Note: The laboratory reports describe studies conducted for the product, UCARSAN 414 Sanitizer (also known as UCARCIDE 14 Antimicrobial). The applicant's letter to EPA (dated April 7, 2006) states that the products, UCARSAN 414 Sanitizer and UCARCIDE 42 Antimicrobial, have the same components and end-use dosing of the active ingredient. Therefore, the efficacy studies conducted for the product, UCARSAN 414 Sanitizer, may be used to establish efficacy for the product, UCARCIDE 42 Antimicrobial, which is the subject of this efficacy report.

## II USE DIRECTIONS

The product is designed for sanitizing hard, non-porous surfaces such as cages, floors, mixing equipment, packing and packaging equipment, product transfer lines, storage tanks, transport vehicles, and walls. The label indicated that the product is incompatible with aluminum, galvanized iron, steel, tin, and zinc. The label indicated that the product may be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment. Directions on the proposed label provided the following information regarding preparation and use of the product as a sanitizer:

> Prepare a use solution by adding 0.14-0.56 fluid ounce of the product per gallon of water (0.06-0.24% active ingredient). For application against Foot and Mouth Disease virus and Porcine circovirus, prepare a use solution by adding 0.28-0.69 fluid ounce of the product per gallon of water (0.1-0.25% active ingredient). Thoroughly saturate surfaces with the use solution using a mop or by spraying. Allow to stand for at least 5 minutes (at least 10 minutes for Foot and Mouth Disease virus), or until thoroughly dried.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least $10^4$ from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

## IV SYNOPISIS OF SUBMITTED EFFICACY STUDIES

**1. MRID 468181-01 "Virucidal Evaluation of UCARCIDE 250 Antimicrobial, UCARSAN Sanitizer 420, UCARSAN 414 Sanitizer, and GX + 10% Low Foam (G-cide) for Use on Inanimate Environmental Surfaces: Test for Efficacy Against Highly Pathogenic Avian Influenza Virus (HPAI, H5N1)," by Mary Beth Minyard. Study conducted at Southern Research Institute. Study completion date – April 3, 2006. Project Number 11483.01.**

Note: This laboratory report describes testing for 4 different products. The following summary describes studies using the product, UCARSAN 414 Sanitizer.

This study was conducted against Highly Pathogenic Avian Influenza (HPAI) virus (Strain A/VN/1203/2004; Subtype H5N1; obtained from Alexander Klimov, PhD, Centers for Disease Control, Atlanta, GA), using 9-11 day old embryonated chicken eggs (obtained from Charles River) as the host system. Two lots (Lot Nos. RL1555S4G1 and TD0455S4G3) of the product, UCARSAN Sanitizer 414 Sanitizer, were tested according to Southern Research Institute Protocol "Virucidal Efficacy Evaluation of UCARSAN Sanitizer 420, UCARSAN 414 Sanitizer, UCARCIDE 250 Antimicrobial and GX+ 10% Low Foam for Use on Inanimate Environmental Surfaces: Test for Efficacy against Highly Pathogenic Avian Influenza Virus (H5N1)," dated September 12, 2005 (copy provided). A 500 ppm use solution was prepared by diluting 345 µl of the product to 100 ml with 100±5% ppm AOAC synthetic hard water (titrated at 102.5 ppm; 0.05% active). A 1000 ppm use solution was prepared by diluting 690 µl of the product to 100 ml with 100±5% ppm AOAC synthetic hard water (titrated at 102.0 ppm; 0.10% active). The stock virus culture was adjusted to contain a 5% organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 25 minutes at 23-25°C at 30-33% humidity. For each lot of product, separate dried virus

films were exposed to 2.0 ml of the use solution for 5 minutes at 23-25°C at 30-33% humidity. After the contact period, the virus-disinfectant mixture was neutralized with 2.0 ml of 2X Hank's Balanced Salt Solution containing 50% fetal bovine serum. The plates were scraped with a cell scraper to re-suspend the contents. After re-suspension, an additional 1:5 dilution was prepared, using 1X Hank's Balanced Salt Solution. Ten-fold serial dilutions were then prepared, using 1X Hank's Balanced Salt Solution. Embryonated eggs were candled prior to use to determine embryo viability. Viable embryonated eggs were inoculated intra-allantoically in quadruplicate with 0.2 ml of the dilutions. The eggs were incubated for 4 days at ~37°C. The eggs were candled daily during incubation. Following incubation, the samples were assayed for infectivity. Controls included an inoculated and uninoculated control and those for embryo toxicity, virus titer, and neutralization. The 50% egg lethal dose ($ELD_{50}$) and the 50% Toxic Dose ($TD_{50}$) were calculated by the method of Reed and Muench.

Note: Protocol deviations/amendments reported in the study were not significant, as documented.

Note: The laboratory provided data for a failed trial set up on October 27, 2005 for a 1000 ppm use solution. In that trial, inconsistent results were observed in the $10^{-3}$ dilutions. The results were considered unsatisfactory, and testing was repeated on November 21, 2005. These data were not used to evaluate efficacy of the test product. See Appendix A of the laboratory report.

**2. MRID 468181-02 "Virucidal Effectiveness Test, Glutaraldehyde Based Products, Foot and Mouth Disease Virus" for UCARSAN 414 Sanitizer, UCARCIDE 250 Antimicrobial, and UCARSAN Sanitizer 420, by Philip Keel. Study conducted at the Institute for Animal Health. Study completion date – May 13, 2005. Project Number DISP 01/04 A-F.**

Note: This laboratory report describes testing for 3 different products. The following summary describes studies using the product, UCARSAN 414 Sanitizer.

This study was conducted against Foot and Mouth Disease virus (Strain OBFS 1860; source not specified), using BHK-21 cells (source not specified) as the host system. Two lots (Lot Nos. RL 1555S4G1 and RI 0355S4G1) of the product, UCARSAN 414 Sanitizer, were tested according to a method designed by the Institute of Animal Health and adopted by the United Kingdom=s Department for Environment, Food and Rural Affairs for the UK registration of disinfectants. The stock virus culture contained a 1% organic soil load (fetal calf serum). Three different use solutions of the product were prepared – a 500, 1000, and 2500 ppm use solution. A viral suspension was prepared by mixing 0.5 ml of the test organism with 4.5 ml of 342 ppm hard water supplemented with 1% fetal calf serum. For each product lot, 1 ml of the viral suspension and 1 ml of the use solution was added to 8 ml of sterile 342 ppm hard water (containing 1% fetal calf serum). The solution pH was measured and recorded immediately upon mixing. Each mixture was held for 10 minutes at 4°C. The 500 and 1000 ppm mixtures were also held for 10 minutes at 25°C. After exposure, five serial ten-fold dilutions of the mixtures were prepared in Cell Culture Medium. The medium was removed from fifteen 6-well plates containing BHK-21 cells. The cells were washed with phosphate buffered saline and 0.2 ml of each dilution was inoculated into three separate well plates. 2 ml of Noble agar overlay medium was added to each well of the plates. The subcultures were incubated for 48 hours at 37°C. Following incubation, 2 ml of Methylene Blue Stain was

added to each well and the plates were incubated at room temperature for another 24 hours. After incubation, the agar was washed from the plates. The plates were examined for the presence of plaques to confirm or rule out the presence of the test organism. Controls included those for cytotoxicity and an untreated control. Calculation methods were not specified.

Note: The Statement of No Data Confidentiality Claims states that "[t]hese data may be considered confidential in countries outside the United States."

Note: The study was not conducted in compliance with GLP standards set forth in 40 CFR 160.

**3. MRID 468181-03 "Virucidal Efficacy Test, Glutaraldehyde-Based Products," Virus: SARS-associated Coronavirus for UCARCIDE 250 Antimicrobial, UCARSAN Sanitizer 420, and UCARSAN 414 Sanitizer, by Lisa M. Lundberg. Study conducted at MicroBioTest, Inc. Study completion date – September 20, 2005. Laboratory Project Identification Number 510-104.**

Note: This laboratory report describes testing for 3 different products. The following summary describes studies using the product, UCARSAN 414 Sanitizer.

This study was conducted against Severe Acute Respiratory Syndrome (SARS)-associated Coronavirus (obtained from ZeptoMetrix) using cultures of Vero E6 cells (obtained from ZeptoMetrix) as the host system. Two lots (Lot Nos. RI0355S4G1 and RL1555S4G1) of the product, UCARSAN 414 Sanitizer, were tested according to MicroBioTest Protocol "Virucidal Efficacy Test, Glutaraldehyde-Based Products, SARS-associated Coronavirus," dated August 12, 2004 (copy provided). A 500 ppm use solution was prepared by diluting 345 µl of the product to 100 ml with 100±2.9% ppm AOAC synthetic hard water (titration results not provided; 0.05% active). A 1000 ppm use solution was prepared by diluting 690 µl of the product to 100 ml with 100±2.9% ppm AOAC synthetic hard water (titration results not provided; 0.1% active). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 40 minutes at room temperature. For each lot of product, separate dried virus films were exposed to 2.0 ml of the use solution for 5 minutes at 21°C. After the contact period, the virus-disinfectant mixture was neutralized with 2.0 ml of fetal bovine serum containing 0.1% glycine. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using RPMI 1640 containing 10% fetal bovine serum. Vero E6 cells were inoculated in quadruplicate with an unspecified amount of selected dilutions and incubated for 40 minutes at 36±2°C to allow for viral adsorption. Post-adsorption, the samples were aspirated, washed, and re-fed with cell culture medium. The cultures were then incubated for 7-10 days at 36±2°C. Post-incubation, the cultures were examined for the presence or absence of unspecified cytopathic effects. Controls included those for cell viability/sterility, plate recovery, neutralizer effectiveness, cytotoxicity, and cytotoxicity-related viral interference. The 50% cell culture infectious dose ($CCID_{50}$) was determined using the method of Reed and Muench.

Note: Protocol deviations/amendments reported in the study were not significant, as documented.

**4. MRID 468181-04 "Virucidal Effectiveness Test, Glutaraldehyde-Based Products," Virus: Porcine circovirus for UCARCIDE 250 Antimicrobial, UCARSAN 414 Sanitizer, UCARSAN Sanitizer 420, and DBNPA 100 PTECH, by M. Khalid Ijaz. Study conducted at MicroBioTest, Inc. Study completion date – November 3, 2004. Laboratory Project Identification Number 510-102.**

Note: This laboratory report describes testing for 4 different products. The following summary describes studies using the product, UCARSAN 414 Sanitizer.

This study was conducted against Porcine circovirus (strain not specified; obtained from American BioResearch Laboratories) using cultures of PT-1 cells (obtained from American BioResearch Laboratories) as the host system. Two lots (Lot Nos. RI0355S4G1 and RL1555S4G1) of the product, UCARSAN 414 Sanitizer, were tested according to MicroBioTest Protocol "Virucidal Effectiveness Test, Glutaraldehyde-Based Products, Porcine circovirus," dated January 19, 2004 (copy provided). A 500 ppm use solution was prepared using 100 ppm AOAC synthetic hard water (titration results not provided; 0.05% active). A 1000 ppm use solution was prepared using 100 ppm AOAC synthetic hard water (titration results not provided; 0.1% active). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at room temperature. For each lot of product, separate dried virus films were exposed to 2.0 ml of the product at 20-24°C. The 0.05% active use solution was tested with a contact time of 5 and 10 minutes. The 0.1% active use solution was tested with a contact time of 5 minutes. After the contact period, the virus-disinfectant mixture was neutralized with 2.0 ml of fetal bovine serum containing 0.1% glycine. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephacryl columns, and diluted serially in Minimum Essential Medium Eagle containing 10% fetal bovine serum. PT-1 cells were inoculated in quadruplicate with an unspecified amount of selected dilutions and incubated for 20-30 hours at 37±2°C in 5±1% $CO_2$ to allow for viral adsorption. Post-adsorption, the mixtures were aspirated, washed, and re-fed with cell culture medium. The cultures were then incubated for 5-7 days at 37±2°C in 5±1% $CO_2$. Post-incubation, the cultures were assayed by an immunofluorescence assay. Controls included those for cell viability/sterility, plate recovery, column titer, virus stock titer, neutralizer effectiveness, cytotoxicity, and cytotoxicity-related viral interference. The 50% fluorescent focus forming unit dose per ml ($FFFUD_{50}$/mL) was determined using the method of Reed and Muench.

Note: The study was conducted according to GLP standards with the following exception: Not all information was documented in strict compliance with GLP standards.

Note: Protocol deviations/amendments reported in the study were not significant, as documented.

Note: The copy of the protocol provided appears to be a draft, as it contains handwritten comments.

V RESULTS

| MRID Number | Organism | Results | | | Plate Recovery Control |
|---|---|---|---|---|---|
| | | | Lot No. RL1555S4G1 | Lot No. TD0455S4G3 | |
| 468181-01 | Avian influenza (H5N1) virus 0.05% active 5 minutes | $10^{-2}$ to $10^{-5}$ dilutions | Complete inactivation | Complete Inactivation | $10^{6.5}$ $ELD_{50}$/0.2 ml |
| | | $ELD_{50}$/0.2 ml | $<10^{2.0}$ | $<10^{2.0}$ | |
| 468181-01 | Avian influenza (H5N1) virus 0.1% active 5 minutes | $10^{-2}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation | $10^{6.2}$ $ELD_{50}$/0.2 ml |
| | | $ELD_{50}$/0.2 ml | $<10^{2.0}$ | $<10^{2.0}$ | |

| MRID Number | Organism | Results | | | Plate Recovery Control |
|---|---|---|---|---|---|
| | | | Lot No. RI0355S4G1 | Lot No. RL1555S4G1 | |
| 468181-03 | SARS-associated Coronavirus 0.05% active 5 minutes | $10^{-2}$ dilution | Cytotoxicity | Cytotoxicity | $10^{5.50}$; $10^{5.67}$; $\geq 10^{6.33}$ $CCID_{50}$/ml |
| | | $10^{-3}$ to $10^{-7}$ dilutions | Complete inactivation | Complete Inactivation | |
| | | $CCID_{50}$/ml | $10^{2.50}$ | $10^{2.50}$ | |
| | | Log reduction | 3.00 to 3.83 | 3.00 to 3.83 | |
| 468181-03 | SARS-associated Coronavirus 0.1% active 5 minutes | $10^{-2}$ dilution | Cytotoxicity | Cytotoxicity | $10^{5.50}$; $10^{5.67}$; $\geq 10^{6.33}$ $CCID_{50}$/ml |
| | | $10^{-3}$ to $10^{-7}$ dilutions | Complete inactivation | Complete Inactivation | |
| | | $CCID_{50}$/ml | $10^{2.50}$ | $10^{2.50}$ | |
| | | Log reduction | 3.00 to 3.83 | 3.00 to 3.83 | |
| 468181-04 | Porcine circovirus 0.05% active 5 minutes | $10^{-2}$ to $10^{-5}$ dilutions | CPE | CPE | $10^{5.50}$ $FFFUD_{50}$/ml |
| | | $10^{-6}$ to $10^{-7}$ dilutions | Complete inactivation | Complete Inactivation | |
| | | $FFFUD_{50}$/ml | $10^{4.67}$ | $10^{4.77}$ | |
| | | Log reduction | 0.83 | 0.73 | |
| 468181-04 | Porcine circovirus 0.1% active 5 minutes | $10^{-2}$ to $10^{-7}$ dilutions | Complete inactivation | Complete Inactivation | $10^{5.50}$ $FFFUD_{50}$/ml |
| | | $FFFUD_{50}$/ml | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ | |
| 468181-04 | Porcine circovirus 0.05% active 10 minutes | $10^{-2}$ to $10^{-3}$ dilutions | CPE | CPE | $10^{5.50}$ $FFFUD_{50}$/ml |
| | | $10^{-4}$ to $10^{-7}$ dilutions | Complete inactivation | Complete Inactivation | |
| | | $FFFUD_{50}$/ml | $10^{3.00}$ | $10^{3.50}$ | |
| | | Log reduction | 2.5 | 2.00 | |

| MRID Number | Organism | Dilution | Test Conditions | Results | |
|---|---|---|---|---|---|
| | | | | Lot No. RL 1555S4G1 | Lot No. RI 0355S4G1 |
| 468181-02 | Foot and Mouth Disease virus | 500 ppm | 4°C<br>25°C | Fail<br>Fail | Fail<br>Fail |
| | | 1000 ppm | 4°C<br>25°C | Fail<br>Pass | Fail<br>Pass |
| | | 2500 ppm | 4°C | Pass | Pass |

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, UCARSAN 414 Sanitizer (a comparable formulation to the product, UCARCIDE 42 Antimicrobial, when diluted according to label directions), as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load and 100 ppm hard water for a contact time of 5 minutes at 0.05 to 0.1% active:

| | |
|---|---|
| Avian influenza (H5N1) virus | MRID No. 468181-01 |
| SARS-associated Coronavirus | MRID No. 468181-03 |

Recoverable virus titers of at least $10^4$ were achieved. In studies against Avian influenza (H5N1) virus, cytotoxicity was not observed. Complete inactivation was indicated in all dilutions tested. In studies against SARS-associated Coronavirus, cytotoxicity was observed in the $10^{-2}$ dilutions. Complete inactivation was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

2. The submitted efficacy data (MRID No. 468181-04) support the use of the product, UCARSAN 414 Sanitizer (a comparable formulation to the product, UCARCIDE 42 Antimicrobial, when diluted according to label directions), as a disinfectant with virucidal activity against Porcine circovirus on hard, non-porous surfaces in the presence of a 5% organic soil load and 100 ppm hard water for a contact time of 5 minutes at 0.1% active. A recoverable virus titer of at least $10^4$ was achieved. Cytotoxicity was not observed. Complete inactivation was indicated in all dilutions tested.

3. The submitted efficacy data (MRID No. 468181-02) do not support the use of the product, UCARSAN 414 Sanitizer (a comparable formulation to the product, UCARCIDE 42 Antimicrobial, when diluted according to label directions), as a disinfectant with virucidal activity against Foot and Mouth Disease virus in the presence of 342 ppm hard water and a 1% organic soil load for a contact time of 10 minutes at a 500, 1000, or 2500 ppm dilution. Although the laboratory stated that the following tests "passed," DIS/TSS-7 requirements were not met:

2500 ppm (0.25% active) at 4°C
1000 ppm (0.1% active) at 25°C

Only three wells, not the required four wells, were tested at each dilution. In addition, the actual product contact time cannot be determined because a neutralizer step was

not performed. The applicant did not provide sufficient data to evaluate the validity of the efficacy testing, including:

- Results of cytotoxicity testing for all dilutions tested.
- The method used to calculate viral titers.
- Complete results for each determination and for all serial dilutions in the format provided in Table 1 of EPA DIS/TSS-7.

The study was not conducted in compliance with GLP standards set forth in 40 CFR 160, as no GLP-certified labs currently conduct testing against Foot and Mouth Disease virus.

## VII RECOMMENDATIONS

1. The proposed label claims that the product, UCARCIDE 42 Antimicrobial, is an effective sanitizer for use on non-food contact surfaces against Avian influenza (H5N1) virus and SARS-associated Coronavirus for a contact time of 5 minutes at a dilution of 0.06 to 0.24% active. Data provided by the applicant support these claims.

2. The proposed label claims that the product, UCARCIDE 42 Antimicrobial, is an effective sanitizer for use on non-food contact surfaces against Porcine circovirus for a contact time of 5 minutes at a dilution of 0.1 to 0.25% active. Data provided by the applicant support this claim.

3. The proposed label claims that the product, UCARCIDE 42 Antimicrobial, is an effective sanitizer for use on non-food contact surfaces against Foot and Mouth Disease virus for a contact time of 10 minutes at a dilution of 0.1 to 0.25% active. Data provided by the applicant do not support this claim. As discussed in the Conclusions section of this efficacy report, efficacy data provided do not meet DIS/TSS-7 requirements. Efficacy tests against this virus were not conducted in compliance with GLP standards set forth in 40 CFR 160.

4. Although the "Storage and Handling" section of the proposed label lists materials that are compatible and incompatible with the product, the label does not list the types of surfaces (e.g., glass, painted wood, stainless steel) on which the product is recommended for use. DIS/TSS-15 requires that this information be included on the product label; this information is not optional.

5. Making the following changes would improve the proposed label:

- Under the "Product Dilution" section, change "Corona virus" to read "Coronavirus" and change "Circo Virus" to read "circovirus."

- Add a new "step 1" under the "Sanitizing Non-Food Contact Surfaces, Farm, Animal, and Poultry Housing Facilities and Equipment" section that reads: "Remove filth and soil deposits from surfaces prior to treatment." Note: If, and

when, Foot and Mouth Disease virus claims are approved for the label, include the following statement in the new "step 1:" "Pre-clean surfaces with a suitable detergent and rinse with water." This revision is necessary because surfaces must be pre-cleaned prior to using the product. Efficacy testing against Foot and Mouth Disease virus was not conducted in the presence of moderate soil loads.]

- Under the "Farm Equipment and Animal Housing Buildings" section, revise "step 4" to read: "Allow to stand for at least 5 minutes, or for a longer time depending on the organisms being treated. (See Product Dilution, above.)"

- Under the "Hatchers, Setters, and Chick Processing Facilities" section, revise the second to last sentence in "step 1" to read: "Allow to stand for at least 5 minutes, or for a longer time depending on the organisms being treated. (See Product Dilution, above.)"

- [Note: If, and when, Foot and Mouth Disease virus claims are approved for the label), revise the "Trays, Racks, Carts . . ." section and the "Trucks and Other Vehicles" section to read: "Remove all filth and heavy debris from surfaces by scraping or washing. Pre-clean surfaces with a suitable detergent and rinse with water." This revision is necessary because surfaces must be pre-cleaned prior to using the product. Efficacy testing against Foot and Mouth Disease virus was not conducted in the presence of moderate soil loads.]

- Under the "Trays, Racks, Carts . . ." section and the "Trucks and Other Vehicles" section, revise the directions to include a contact time.

- Note: If, and when, Foot and Mouth Disease virus claims are approved for the label revise the "Sanitizing Non-Food Contact Surfaces, Industrial Equipment and Buildings" section by adding a sentence such as: "Pre-clean surfaces with a suitable detergent and rinse with water." This revision is necessary because surfaces must be pre-cleaned prior to using the product. Efficacy testing against Foot and Mouth Disease virus was not conducted in the presence of moderate soil loads.]

- Under the "Sanitizing Non-Food Contact Surfaces, Industrial Equipment and Buildings" section, revise the second to last sentence to read: "Allow to stand for at least 5 minutes, or for a longer time depending on the organisms being treated. (See Product Dilution, above.)"

6. Information identifying the doses (i.e., % active, ppm active, ounces per gallon) for the industrial applications is inconsistent. For example, the dilution rate for the "Water Floods" application states to add 100-5000 ppm of product (0.09-4.5 gallons per 1000 gallons of water). A 100-5000 ppm solution is equivalent to a 0.01-0.5% active solution; whereas, a 0.09-4.5 gallons/1000 gallons solution is equivalent to a 0.004-0.22% active solution. The doses for all industrial applications need to be reviewed.

7. On the proposed label, the following statement " A Highly Effective Microbiocide for Use in Controlling Bacteria including slime forming bacteria ( Pseudomonas sp., Enterobacter sp., Klebsiella sp., Acinetobacter sp., Serratia sp., and Bacillus sp.,)" must be revised or removed completely. The Agency views "slime-forming" organisms as non-public health. The bacteria listed are public health organisms, as supported by their

placement in the section "Sanitizing Non-Food Contact Surfaces, Farm, Animal, and Poultry Housing Facilities and Equipment," on the proposed label.

8. Please remove the following bacteria from the proposed label, as efficacy data was not submitted or accepted for these organisms: Enterobacter sp., Klebsiella sp., Acinetobacter sp., Serratia sp., and Bacillus sp.